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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE NATIONAL PRESCRIPTION

OPIATE LITIGATION

This document relates to:

Track One Cases

MDL 2804

Case No. 17-md-2804

Hon. Dan Aaron Polster

**PLAINTIFFS' MEMORANDUM OF LAW IN SUPPORT OF MOTION FOR
PARTIAL SUMMARY ADJUDICATION THAT DEFENDANTS DID NOT
COMPLY WITH THEIR DUTIES UNDER THE FEDERAL CONTROLLED
SUBSTANCES ACT TO REPORT SUSPICIOUS OPIOID ORDERS AND NOT
SHIP THEM**

(Corrected)

June 28, 2019

3. *Rite Aid Developed, But Never Implemented, a Suspicious Order Monitoring System*

Recognized the shortcoming of its distribution system, in 2013, Rite Aid sought to develop a suspicious order monitoring system. Ex. 423 [Rite_Aid_OMDL_0040184-98]. In documenting such efforts, Rite Aid stated as follows:

The purpose of this project is to develop effective controls against the diversion of controlled substances and conduct adequate due diligence to ensure that controlled substances distributed from the Distribution Centers are for legitimate patient needs. Rite Aid must ensure compliance with 21 U.S.C. 823 and/or C.F.R. 1307.74(b) to detect and report suspicious orders of controlled substances through the Distribution Centers.

Id. (emphasis added). In the end, however, Rite Aid never adopted the new SOM because they stopped distributing controlled substances before this system could be implemented.

O. HBC Failed to Comply with Its CSA Duties to Maintain Effective Controls against Diversion

1. *The Undisputed Evidence Shows that Defendants Failed to Develop and Maintain a System to Identify Suspicious Orders of Opioids*

(a) Defendant HBC Service Company Had No Meaningful System to Identify Suspicious Orders of Opioids

From November 2009 until October 2014, HBC Service Company (HBC) distributed large volumes of controlled substances into Cuyahoga and Summit Counties, including distribution of Hydrocodone Combination Products (HCPs).⁴¹⁸ HBC stopped shipping HCPs in October 2014, when HCPs were reclassified as Schedule II drugs under the Controlled Substances Act.⁴¹⁹ Over nearly a five (5) year period, HBC shipped millions of dosage units of HCPs into Cuyahoga and Summit Counties and the cities therein.⁴²⁰

By its own admission, HBC reported only two orders as suspicious, and both orders were for a drug that is not at issue in this litigation.⁴²¹ HBC did not report to the DEA a single suspicious order

⁴¹⁸Ex. 424, *HBC Service Company's Amended Responses to Plaintiffs' (First) Set of Combined Discovery Requests*, December 29, 2018, Request 2, p. 8: "...[HBC] did not distribute any relevant Schedule III opioids (i.e. those that were later reclassified as Schedule II) until November 2009..."

⁴¹⁹ *Id.* "...[HBC] stopped distributing relevant Schedule III opioids in October 2014..."

⁴²⁰ For detailed figures on distribution into relevant jurisdictions, see tables below.

⁴²¹ One of those two orders was more than two (2) years after HBC stopped distributing HCPs. *HBC Service Company's Amended Responses to Plaintiffs' (First) Set of Combined Discovery Requests*, December 29, 2018, Request 3, p. 11, see Ex. 424: "On

of HPCs, even though orders of unusual size were regularly being shipped into Cuyahoga and Summit Counties, as explained below. HBC also could not identify a single shipment that was stopped for being suspicious; instead, HBC shipped orders to their customers even if they had been flagged as suspicious. No reasonable fact-finder could conclude that a system with virtually no oversight was adequate. HBC had a patently inadequate system of detection.

- (b) HBC had no written SOM policy until August 1, 2014, only two (2) months before it stopped shipping opioids at issue

For nearly the entire five-year period that HBC distributed HCPs, it had no written suspicious order monitoring (SOM) policy. By HBC's own admission, its earliest written SOM policy is dated August 1, 2014.⁴²² HBC stopped distributing controlled substances at issue in October 2014.⁴²³ HBC, then, operated as a distributor of controlled substances without a written SOM policy for all but two (2) months.

Further, HBC's August 1, 2014 policy does not identify how its SOM system operated, but rather outlines the process for reporting suspicious product orders.⁴²⁴ This "Inventory Controls Policy" appears to leave most of the responsibility for identifying suspicious orders on parent company Giant Eagle, which also owns all of HBC's customers, Giant Eagle Pharmacies. The policy states:

- HBC Pharmacy group will be contacted by GE Pharmacy team if they suspect any suspicious ordering by a Giant Eagle Pharmacy.
- HBC, as directed by the GE Pharmacy team, will delete or restrict any order that has been identified as suspicious.
- HBC will prepare and communicated any history of suspicious orders to the GE Pharmacy team as requested.

December 5, 2013, HBC identified a suspicious order for buprenorphine 8mg SL tab (the "December 5, 2013 Suspicious Order") and reported the order to the DEA on the same day." The other suspicious order noted on that same page was actually more than two (2) years after HBC stopped distributing drugs at issue in this litigation.

⁴²² See: Ex. 425, HBC_MDL00133445 "HBC Service Company Inventory Controls Policy (Version 1)" August 1, 2014

⁴²³ Ex. 424, *HBC Service Company's Amended Responses to Plaintiffs' (First) Set of Combined Discovery Requests*, December 29, 2018, Request 2, p. 8: "...[HBC] stopped distributing relevant Schedule III opioids in October 2014..."

⁴²⁴ Ex. 425, HBC_MDL00133445 "HBC Service Company Inventory Controls Policy (Version 1)" August 1, 2014

- The GE Pharmacy team will, in conjunction with the HBC Pharmacy information, notify the DEA within the prescribed 3 day time limit.⁴²⁵

The policy does not elaborate on how to identify a suspicious order, nor does HBC's warehouse supervisor recall any specific training to identify suspicious orders.⁴²⁶

Further, HBC admits in its written discovery responses that it provided no "educational, information and/or other programs to any Customer and/or pharmacy/dispenser that it owns and/or controls or *other Person*, that address diversion, safety, efficacy, misuse and/or prescription of Schedule II Opioids."⁴²⁷

HBC thus has failed on its obligation to have an adequate system in place to identify suspicious orders.

- (c) HBC first monitored ordering thresholds in October 2013 in a manner it admits was flawed

HBC's attempt to identify orders of unusual size was deeply flawed. On October 15, 2013, after approximately four (4) years of distributing HCPs, HBC finally began to aggregate its customers' controlled substance orders and apply a rudimentary threshold to identify suspicious ordering behavior.⁴²⁸ From that point until it stopped distributing HCPs, HBC produced a daily spreadsheet that identified shipments, each of which had already been shipped to the pharmacy, that exceeded the chain-wide ordering threshold for the particular drug. HBC admitted that the threshold report kept track of the shipped quantities, not the ordered quantities, further emphasizing the lack of pre-shipping due diligence.⁴²⁹

⁴²⁵ *Id.*

⁴²⁶ See Ex. 426, Rogos Dep. Tr. at 71:10-72:2; 77:23-78:13; 141:2-22.

⁴²⁷ Ex. 427, HBC-4, *HBC Service Company's Supplemental Answers to Plaintiff's First Set of Interrogatories to HBC Service Company*, March 4, 2019, Inter. No. 23, p. 42 (emphasis supplied)("other Person" would include warehouse personnel and other employees)

⁴²⁸ Ex. 428, Tsipakis Dep. Tr. at 117:18-119:17

⁴²⁹ Ex. 429, Tsipakis Dep. Tr. 165:14-168:2

HBC's thresholds were also deficient. HBC set thresholds for controlled substances by taking the average amount *all* of its customers ordered and multiplying by three (3). The effect is that when a customer whose orders for a controlled substance in a month exceeded 300% of the average HBC customer, it was flagged on HBC's threshold report.⁴³⁰ HBC admits setting thresholds by a chain-wide average can result in both false positives (large-volume store consistently orders more than threshold) and false negatives (small-volume stores' relatively large order does not exceed chain-wide threshold).⁴³¹ This means that a customer which does a sufficiently large amount of business with HBC might exceed the set threshold. Conversely, a small customer's unusually large order is likely not sufficiently large to clear the 300% average mark, leaving its relatively large orders unscrutinized.

(d) Defendant HBC Failed to Follow Its Own Suspicious Order Policies

HBC's first written SOM policy was adopted on August 1, 2014 and consisted of four short bullet points which were part of a larger policy.⁴³² This policy relied on Giant Eagle's corporate office to alert HBC if Giant Eagle (GE) pharmacies engaged in suspicious ordering.⁴³³

The policy also directed that HBC would prepare and communicate any history of suspicious orders to the GE Pharmacy team "as requested," not making such a report a matter of course. The policy then required GE Pharmacy team, *not HBC*, to notify the DEA "with in [sic] the prescribed three day time limit."⁴³⁴ In this way, HBC's actual policy was to delegate its DEA reporting responsibility to its customers' owner.

HBC's written SOM policy did not result in significant changes to HBC practices. HBC did not report a suspicious order while this written policy was in effect prior to it ceasing to distribute

⁴³⁰ Ex. 430, Tsipakis Dep. Tr. 118:2–12

⁴³¹ Ex. 431, Tsipakis Dep. Tr. 247:8–248:3

⁴³² Ex. 425, HBC_MDL00133445 "HBC Service Company Inventory Controls Policy (Version 1)" August 1, 2014

⁴³³ *Id.*

⁴³⁴ *Id.*

controlled substances in October 2014.⁴³⁵ Giant Eagle did not revise the policy until after HBC stopped distributing controlled substances.⁴³⁶

- (e) HBC did not systemically investigate the orders its threshold monitoring system did flag

HBC witnesses have acknowledged that they have no recollection of specific investigations, that they had no systematic process in place to investigate flagged orders, and that they have no log or report to document that an investigation occurred for each flagged order.⁴³⁷ Also, the emails and other documents produced indicated that only a handful of investigations occurred at periodic times and that such investigations were cursory at best.⁴³⁸

No reasonable fact-finder could conclude HBC's system was adequate given its lack of documented due diligence on orders identified as suspicious.

2. *The Undisputed Evidence Shows that HBC Failed to Report Suspicious Orders in Summit and Cuyahoga Counties*

In December 2013, HBC reported its only suspicious order to the DEA during its time shipping controlled substances from November 2009 and October 2014.⁴³⁹ That suspicious order was for buprenorphine, which is an opioid, but not currently a Schedule 2 controlled substance under the Controlled Substance Act. It is not surprising that HBC did not report any suspicious orders prior to October 2013, because as explained above it did not track its pharmacy-customers' orders against a threshold during that period.

⁴³⁵ See Ex. 424, *HBC Service Company's Amended Responses to Plaintiffs' (First) Set of Combined Discovery Requests*, December 29, 2018, Request 3, p. 11 (suspicious order was reported December 2013, before its written policy was in place after August 1, 2014).

⁴³⁶ See Ex. 432, HBC_MDL00004209, April 2015 "Inventory Control SOM Policy"

⁴³⁷ Ex. 433, Tsipakis Dep. Tr. at 107:4–108:23; Ex. 434, Mollica Dep. Tr. 220:23–221:6; Ex. 435, Millward Dep. Tr. 179:23–180:8; but see: Ex. 436, Millward Dep. Tr. 257:13–259:8.

⁴³⁸ Ex. 437, HBC_MDL00039223 (Jan. 10, 2014); Ex. 438, HBC_MDL00058099; Ex. 439, HBC_MDL00090010 (July 8, 2014)

⁴³⁹ As discussed above, Ex. 424, *HBC Service Company's Amended Responses to Plaintiffs' (First) Set of Combined Discovery Requests*, December 29, 2018, Request 3, p. 11.

3. *The Undisputed Evidence Shows that HBC Shipped Orders into Summit and Cuyahoga Counties in Violation of Their CSA Duties*

- (a) HBC shipped the majority of its CT1 drugs without a threshold monitoring system: 84% of units into Cuyahoga County and 82% of units into Summit County had no threshold order review

Before implementing its first threshold report on October 15, 2013, HBC shipped large amounts of CT1 drugs into Summit and Cuyahoga Counties with no threshold monitoring⁴⁴⁰ and with no written SOM policy⁴⁴¹:

Jurisdiction	Units Shipped (11/12/2009–10/14/2013)	Bates Service
Cuyahoga County	10,684,835	HBC_MDL00189212
Summit County	8,700,931	HBC_MDL00189213

After its threshold program was in place on October 15, 2013, HBC shipped the following amounts of CT1 drugs into Summit and Cuyahoga Counties:

Jurisdiction	Units Shipped (10/15/2013–9/30/2014)	Bates Service
Cuyahoga County	1,940,344	HBC_MDL00189212
Summit County	1,822,912	HBC_MDL00189213

As shown in these tables, HBC shipped 84% of its total CT1 drugs into Cuyahoga County and 82% of its total CT1 drugs into Summit County without a threshold program to monitor suspicious orders.⁴⁴²

⁴⁴⁰ Ex. 428, Tsipakis Dep. Tr. at 117:18–119:17, first HBC threshold report was on October 15, 2013

⁴⁴¹ HBC's earliest written SOM policy is from August 1, 2014, See: Ex. 425, HBC_MDL00133445 "HBC Service Company Inventory Controls Policy (Version 1)" August 1, 2014

⁴⁴² These percentages come from dividing the amount for each county in the first chart by a total of both charts (the sum of which represents the total amount HBC distributed into each county):

Cuyahoga County: 10,684,835 / (10,684,835 + 1,940,344) = 0.8463... or 84% of total distribution into Cuyahoga

Summit County: 8,700,931 / (8,700,931 + 1,822,912) = 0.8267 or 82% of total distribution into Summit

No reasonable fact-finder could determine that HBC fulfilled its duties under the Controlled Substances Act (CSA) while shipping over eighteen million (18,000,000) units of opioids at issue in this case with no written SOM policy. Further, no reasonable fact-finder could conclude that HBC fulfilled its duties under the CSA with its admittedly flawed⁴⁴³ threshold system and SOM program.⁴⁴⁴

- (b) HBC admits it never had the ability to automatically stop its controlled substance shipments which exceeded its set threshold

HBC never had the automated ability to stop shipments which exceeded its established threshold for that controlled substance.⁴⁴⁵

HBC also did not *manually* stop suspicious orders from shipping which had been flagged by its threshold report. HBC admitted that its threshold reports tracked already shipped, not ordered, materials⁴⁴⁶ which did not leave an adequate window or process to identify, stop and investigate unusual orders once it became aware of them.

After HBC no longer shipped controlled substances, its parent company Giant Eagle had the opportunity (for its new distribution center) to utilize a third-party system to stop over-threshold orders from shipping. Giant Eagle's Senior Pharmacy Director Adam Zakin declined, claiming it was not worth the expense because the only thing the new system would do was "stop the orders physically if there were a threshold."⁴⁴⁷

⁴⁴³ Ex. 430, Tsipakis Dep. Tr. 118:2–12, showing issues which arise using chain-wide ordering averages (not individual pharmacy averages) when setting threshold levels.

⁴⁴⁴ As discussed above, *HBC Service Company's Amended Responses to Plaintiffs' (First) Set of Combined Discovery Requests*, December 29, 2018, Request 2, p. 11, showing on no relevant suspicious orders identified.

⁴⁴⁵ Ex. 440, Tsipakis Dep. Tr. 201:21–24; 213:8–10, 255:24–256:23.

⁴⁴⁶ Ex. 442, Tsipakis Dep. Tr. 141:3–11

⁴⁴⁷ Ex. 441, HBC_MD00028498, 2016.03.29 email: Adam Zakin, Sr. Director, Pharmacy Administration, replying internally regarding a third-party CS ordering system: "Were you not there? At the end of the day, the only thing it did that our current system would not do, was stop the orders physically if there was a threshold."

No reasonable fact-finder could conclude that a distributor who knowingly declined to employ a system which could stop threshold-exceeding orders from shipping has adequately fulfilled its duties under the CSA.⁴⁴⁸

P. DDM Failed to Comply with Its CSA Duties to Maintain Effective Controls against Diversion

Discount Drug Mart (“DDM”) is an Ohio-based pharmacy chain with 74 retail stores.⁴⁴⁹ DDM shipped Schedule III-V controlled substances from DDM’s distribution center located in Medina, Ohio.⁴⁵⁰ DDM’s shipments included distribution of Hydrocodone Combination Products (HCPs) until approximately 2014, when HCPs were rescheduled to the more restrictive Schedule II.⁴⁵¹ Over nearly a fifteen (15) year period, DDM shipped millions of dosage units of HCPs into Cuyahoga and Summit Counties and the cities therein.⁴⁵² From 2006 to 2014 alone, DDM distributed nearly 12 million dosage units to its pharmacies in Cuyahoga County and over 3.4 million dosage units to its pharmacies in Summit County.⁴⁵³

DDM never reported a single suspicious order to the DEA, despite the fact that orders of unusual size were regularly distributed by DDM, as explained below. Similarly, DDM could not identify a single order that was halted as suspicious; instead, DDM shipped orders it had flagged as suspicious.

DDM admits it had an obligation to the general public to prevent diversion of opioids.⁴⁵⁴ Further, it is undisputed that DDM was legally required to implement a system of effective controls

⁴⁴⁸ The expert opinion of Matthew Greimel is not to the contrary, for two reasons. First, Mr. Greimel does not believe that the no-shipping duty exists, and his opinions are to some extent based on that erroneous legal conclusion. *See* Greimel Report at 11-12. Second, Mr. Greimel reviewed HBC’s written policies, but did not review what HBC actually *did*. For that reason, his report creates no genuine issue of fact. Ex. 443.

⁴⁴⁹ Ex. 444, Briscoe Dep., at 86.

⁴⁵⁰ Ex. 445, Briscoe Dep., at 34-35.

⁴⁵¹ Ex. 446, Briscoe Dep., at 41-42.

⁴⁵² Ex. 447, Report of Craig McCann, Appendix 9 at pp 151, 193.

⁴⁵³ Ex. 448, Report of Craig McCann, Appendix 9 at 3783, 3852.

⁴⁵⁴ Ex. 449, Nameth Dep., at 111.

CONCLUSION

For the foregoing reasons, this Court should grant Plaintiffs' request for summary adjudication and should find, as a matter of law, that during the period 2000-2016, Purdue, Endo, Teva, Mallinckrodt, J&J, Cardinal, McKesson, ABDC, PSI, Walmart, Walgreens, CVS and Rite Aid were all in violation of their duties, under the Controlled Substances Act to maintain effective controls against diversion, to design and operate a system to identify suspicious orders, to report suspicious orders to the DEA and/or to halt shipment of suspicious orders pending investigation.

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Respectfully submitted,

/s/ Paul J. Hanly, Jr.

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